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Trade Policy Monitoring

Bioterrorism: US Outreach and Transparency

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Approved by:
Stan Cohen
U.S. Mission to the European Union, Brussels

Prepared by:
Christine Strossman and Stephanie Frye

Report Highlights:
The US Government carried out extensive outreach in preparation for new rules on bioterrorism affecting imports of food into the United States. There were also many opportunities for stakeholders around the world to provide input as the rules were developed. This report outlines outreach benefiting the European Union and how EU stakeholders have been able to participate in the development of the bioterrorism rules.

Includes PSD Changes: No
Includes Trade Matrix: No
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[E2]

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 includes authority for the U.S. Food and Drug Administration (FDA) to take action to protect the nation's food supply against the threat of intentional or accidental contamination and other food-related public health emergencies. As part of implementing the Bioterrorism Act, FDA has just published two regulations. These measures establish new procedures which will affect some foreign companies that export certain food, feed and live food animals to the United States.

One regulation requires domestic and foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the agency by December 12, 2003. The second regulation requires that prior notice be given to FDA before food is imported or offered for import into the United States. This gives FDA advance information of imported food shipments and allows FDA to target inspections of suspect shipments more effectively to help ensure the safety of imported food products before they enter domestic commerce. In response to comments, substantial changes were made to the proposed rules in order to minimize disruptions to trade.

For more information about the Bioterrorism Act and FDA regulations, see the following web page: http://www.fda.gov/oc/bioterrorism/bioact.html

FDA Outreach in Europe

FDA has conducted extensive outreach activities, both in the U.S. and abroad, including personal attendance at over 100 international and domestic meetings, to provide information about the two new regulations. Below is a timeline indicating the opportunities that have been made available for input from European countries.

On July 17, 2002, FDA began its outreach activities for the regulations under the Bioterrorism Act by issuing a “Dear Colleague” letter to stakeholders, including states, foreign embassies, trade associations, industry, sister agencies, and consumer groups. The letter gave an overview of the provisions in Title III, Subtitle A (Protection of the Food Supply), informed how the Department and FDA would be proceeding, and solicited comments. This letter was issued only one month after the Bioterrorism Act was signed into law, and provided the opportunity for stakeholders to comment before drafting of the proposed regulations began.

In July and August of 2002, FDA also held six constituent briefings with stakeholders that approximately 88 organizations (including 36 embassies) attended in which FDA solicited early public comment the Agency could use as it developed the proposed regulations. In addition, FDA opened a public docket for each regulation and invited preliminary written comments from stakeholders. FDA received over 150 comments during this early comment period that were considered as it developed the proposed regulations.

On January 29, 2003, FDA held a public meeting (via satellite downlink) to discuss the registration and prior notice proposed regulations. Nearly 1,000 participants in the North and South America, and the Caribbean viewed the live broadcast. The meeting was later re-broadcast to Europe to Asia, Africa, and the Pacific. Transcripts of the broadcast are available on FDA’s website in English, French, and Spanish.

On February 3, 2003 FDA and the Department of Treasury (U.S. Customs Service) jointly published the proposed regulations for registration and prior notice and opened a 60-day comment period.

On Feb 10, 2003 FDA presented information on the proposed rules at a meeting held at the Embassy of Greece in Washington, DC for the Agriculture Counselors of the 15 EU Member States, plus representatives from the European Commission. At this meeting, the participants were encouraged to comment on the proposed rules.

On March 5, 2003 FDA senior officials held two outreach meetings in Brussels, Belgium. The first meeting was with European Commission officials and the second session was with approximately 30 industry representatives in the EU. At both sessions, participants were encouraged to comments on the proposed rules.

On April 22, April 28, and May 8, FDA conducted three demonstrations on the web-based food facility registration system for stakeholders. Representatives from foreign governments, domestic industry, and federal agencies attended.

On October 10, 2003, interim final rules on Registration and Prior Notice were published. In the preamble of the rule, FDA addressed the comments received and explained the changes that were made based on the comments. Due to concerns raised by commenters, additional comments were requested by December 24, 2003. Moreover, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the interim final rules, the agency intends to reopen the comment period for an additional 30 days in March 2004.

On October 16th FDA hosted a conference call with the EU Commission to present and answer questions about the new regulations. The additional opportunity to comment was also highlighted.

On October 28th a public meeting was held to explain the rules through a satellite downlink. The meeting was later re-broadcast to Europe to Asia, Africa, and the Pacific. Transcripts of the broadcast are available on FDA's website in English, French, and Spanish.

On November 6th and 7th a seminar was held for foreign embassies, which included a full day of information and presentations on the new rules.

On Nov 21, 2003 a senior FDA official met with EU industry, Commission, and Member State representatives in Brussels to present the interim final rules and answer questions.

On-line resources

In addition, FDA has set up an extensive and informative website that addresses many of the questions that registrants and submitters of prior notice may have at the following address: http://www.fda.gov/oc/bioterrorism/bioact.html. The text of the regulations as well as comments, factsheets, guidelines, Q&A's and help files are among the resources available on this site. In addition to this, a telephone help desk is available or questions may be posed directly to FDA via email.

Compliance Policy

In addition, in order to ensure that trade will not be disrupted by the new regulations, FDA issued a Compliance Policy Guide, available at the following web address: http://www.cfsan.fda.gov/~pn/cpgpn.html. The guide outlines FDA's phased approach for enforcing the regulations, with the focus in the first several months on education rather than strict enforcement.

Responsiveness to EU Concerns

FDA reviewed all comments submitted and took them into account when drafting and revising the regulations. The preambles to the interim final rules on registration and prior notice indicate how the rules were changed based on comments. The following are examples of concerns raised by the EU that were reflected in changes that were made in the interim final rules.

1. The EU questioned how the US would avoid needless expense, bureaucracy and obstacles to trade.

FDA has made a number of changes in the interim final rule that are both consistent with FDA's statutory mandate and that will make it easier and less costly for covered facilities (foreign or domestic) to register. In addition, the interim final rule exempts certain establishments from the registration requirement that, under the rule as proposed, would have been required to register.

FDA is clarifying that having a single US agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes.

The definition of "farm" now states that washing, trimming of outer leaves, and cooling produce are part of harvesting. The definition also now includes facilities that pack or hold food, provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership.

Packaging (when used as a verb) has been defined and means "placing food into the container that directly contacts the food that the consumer receives."

The definition of "retail food establishment" has been revised to be more concise.

FDA has added a definition for "trade name" as "the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product."

2. The EU commented that the requirement that the importer must notify may not reflect business practice in all cases and that the rules should allow the foreign exporter to provide the prior notification.

The interim final rule has been revised to remove the restriction that the submitter of prior notice be the U.S. importer or purchaser. The interim final rule provides that any person with knowledge of the required information may submit prior notice or have it transmitted on their behalf.

3. The EU questioned how the US will deal with the practical aspects of registration.

The FDA has set up a detailed website that aids registrants in the application process. It user-friendly and contains overview, background, and step-by-step registration information. Registration may be done directly on the website at:
http://www.cfsan.fda.gov/~furls/ovffreg.html

The FDA has also extended the timeframe in which registrants must update their registrations from 30 to 60 days of any change in required information. FDA has also deleted the requirement to update optional information previously submitted. Registrants may now also register via fax or CD-ROM in addition to mailed submissions.

4. The EU requested information on risk assessment, on which the Bioterrorism Act is based.

There is a risk assessment available and a complete copy can be found online at: http://www.cfsan.fda.gov/~dms/rabtact.html

5. The EU commented that a better definition of "food" is needed to clarify the scope of application of the measure.

FDA has changed the definition of "food" for purposes of the Bioterrorism Act to exclude food contact substances and pesticides. These are defined in sections 409 (h) (6) of the FD&C Act and in FIFRA (7 U.S.C. 136(u)).

6. The EU commented that a large amount of information is already required for entry through USA customs and questioned whether the FDA is coordinating with other US agencies that have similar initiatives that fulfill the objectives of the prior notice requirement to avoid duplication.

The FDA and CBP plan to provide a single point of data entry, and are committed to the joint implementation of an automated approach to prior notice that will meet the following objectives:

1. Reduce submission of redundant data to the greatest extent possible
2. Build on current operational procedures
3. Implement the law with minimal disruption to current entry practices

On May 27, 2003, FDA and the Bureau of Customs and Border Protection issued a joint press release stating that as a result of continued collaboration, in most circumstances importers will be able to provide prior notice submissions through Customs' Automated Commercial System (ACS), thereby allowing importers to provide required information to both agencies using an integrated process.

FDA proposed that prior notice, amendments, and updates be submitted electronically to FDA through the FDA PN System. The interim final rule provides that prior notice must be submitted electronically, through either CBP's ABI/ACS or the FDA PN System Interface. The interim final rule eliminates submission of duplicative information to FDA by those who can file import entry information through ABI/ACS. FDA and CBP are upgrading and interfacing their respective electronic systems so that information required for prior notice can be submitted through ABI/ACS. Information required by the interim final rule also can be submitted through the FDA PN System Interface.

7. The EU commented that there should be procedures in place in case notifications cannot be made electronically due to computer failure.

The interim final rule provides that if a customs broker's or self-filer's system is not working or if ABI/ACS is not working, prior notice must be submitted through the FDA PN System

Interface. If the FDA PN System Interface or OASIS is not operating, prior notice information must be submitted by e-mail, or by fax to the FDA.

8. The EU called for a provision for reviewing and amending the system so as to ensure that possible negative effects on trade and foreign companies are minimised in practice, in particular in the light of the experience acquired.

The interim final rule provides for additional comments to be submitted by December 24, 2003. Moreover, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the interim final rules, the agency intends to reopen the comment period for an additional 30 days in March 2004.

9. The EU commented that there should be a period of exemption from prosecution for operators who do not register correctly or on time.

FDA published a compliance guide specifying that during the first eight months following December 12, 2003, FDA and CBP plan to focus their resources on education to achieve compliance with the prior notice requirements, rather than imposing penalties for non-compliance. Full details can be found at the following link:
http://www.cfsan.fda.gov/~pn/cpgpn.html

10. The EU commented that the Bioterrorism Act itself was never notified to the WTO nor justified by a risk assessment.

The WTO was notified of the implementation of the Bioterrorism Act on February 6, 2003. The risk assessment that lies behind the act may be found at:
http://www.cfsan.fda.gov/~dms/rabtact.html

11. The EU commented that the US has not provided any impact cost on foreign exporters to the US. The only cost analysis concerns the increased administrative burden on US companies.

Section V of the interim rule, entitled “Analysis of Economic Impacts”, is a helpful tool in cost analysis of Prior Notice. In addition, the interim final rule calls for additional comments by December 24, 2003 specifically relating to the costs for foreign companies.

12. The EU commented that for air-freighted goods the period of notice required is too far in advance and poses a threat to this type of trade.

FDA had proposed that all information required in the prior notice be submitted to FDA no later than 12 noon of the calendar day before the day the article of food arrived at the border crossing in the port of entry (ie. a minimum of 12 hours). The interim final rule was changed such that prior notice must be submitted to FDA no less than 2 hours before arrival by land via road, no less than 4 hours before arrival by air and land via rail, and no less than 8 hours before arrival by water.

13. The EU questioned how importers would know the penalties associated with prior notice before shipment.

FDA has provided on their website a comprehensive guide to violations and the penalties associated with them. As stated before, in the beginning of the adaptation of the new processes, FDA will provide education and communication with importers to prevent violations in the future. The complete guide to violations associated with prior notice may be found at:
http://www.cfsan.fda.gov/~pn/cpgpn.html